K955944

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510(k) Premarket Notification
Summary of Safety and Effectiveness
for Change in Packaging for Osteonics' UHMWPE Components

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Osteonics Corporation 59 Route 17 Allendale, NJ 07401-1677
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Date of Summary Preparation:	February 26, 1996

Device Identification

Proprietary Name:	Osteonics® N_2/Vac Packaging Process
Common Name:	Nitrogen flush/vacuum sealing packaging process
Classification Name and Reference:	Not Applicable

Predicate Device Identification

Devices packaged under the Osteonics® N_2/Vac Packaging Process are substantially equivalent to devices packaged under standard, room air conditions, as well as to devices packaged under the various, other packaging methods recently put forth by other orthopedic implant manufacturers. The following predicate 510(k)s are identified for comparison:

- K934060: Howmedica Acetabular Components Packaging and Manufacturing Methods Change
- K936292: Howmedica Knee Components Packaging and Manufacturing Methods Change
- K940743: DePuy Vacuum Nitrogen (N_2) Flush - Barrier Packaging

Device Description

The devices which are subject to the proposed packaging change are Osteonics implants which contain UHMWPE as a bearing. These devices all have their own, previously established 510(k) clearances. This 510(k) does not address any changes to any component or its device description; it addresses only a change to the way that the devices will be packaged.

Intended Use:

The packaging change which is the subject of this submission does not affect the intended uses of any of the commercially available UHMWPE components subject to the packaging change.

The components which contain UHMWPE as a bearing will be packaged in an inert environment. The packaging method will reduce the oxygen content within the package, thereby retarding oxidation.

Statement of Technological Comparison:

As before, Osteonics' UHMWPE devices will continue to be packaged according to the previously featured "double blister" style method. However, in order to create an inert environment, the component packages will be flushed with Nitrogen and then vacuum sealed. This "N_2/Vac" feature requires the following changes to the package itself:

Changes to Actual Package:

1) The current blister material is replaced with a less gas-permeable material.
2) The current lid stock is replaced with a less gas-permeable lid stock.
3) The inner/outer blister assembly will be placed within a pouch, adding another gas transmission barrier to the final package.

The proposed change in Osteonics' packaging does not affect the device sterility. The sealed inner and outer packaging blisters meet the same package and seal requirements as the traditional Osteonics' packaging. The radiation dose required for sterility is not affected by the new packaging materials, and the sterility assurance level (SAL) of 10^{-6} remains unchanged.